REMARKS

Claims 1, 2, 5, and 42, as amended, claims 3, 4, 7-12, 41, and 43, and new claim 55 are pending in the application. Claims 39 and 49-54 have been cancelled without prejudice or disclaimer. Support for the amendments to the claims can be found in the specification at, for example, page 3, line 20-23; page 13, lines 23-24; page 77, line 27 to page 78, line 5; page 79, lines 22-30; and Figures 1 and 2A-2B. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Objection to the claims

The Office Action contains an objection to claims 13 and 49-54 as failing to comply with 37 C.F.R. § 1.121(c). The Action states that while claim 13 was cancelled in Applicants' response to the Office Action mailed December 2, 2005, the claim was identified in that response as "currently amended" and the text of the cancelled claim was presented in that response. The Action also states that in Applicants' response to the Office Action mailed December 2, 2005, the text of each of new claims 49-54 was underlined.

Applicants cancelled claim 13 in their response to the Office Action mailed December 2, 2005, and the listing of claims in the instant response properly indicates that claim 13 has been cancelled. Applicants have cancelled claims 49-54 in the instant response, and the listing of claims in the instant response properly indicates that claims 49-54 have been cancelled. Applicants contend that the listing of claims in the instant response complies with 37 C.F.R. § 1.121(c), and therefore, respectfully request that this objection be withdrawn. With respect to the cancellation of claims 49-54, Applicants note that independent claim 39 and claims 49-54, which depend directly or indirectly from claim 39, have been cancelled solely in an effort to expedite prosecution of the pending claims to allowance.

Applicants reserve the right to pursue claims directed to the cancelled subject matter in a timely filed continuation or divisional application, or alternatively, reintroduce claims directed to the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance.

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The Office Action also contains an objection to claims 5, 7, 42, 43, 53, and 54 under 37 C.F.R. § 1.75(c) as being of improper form because a multiple dependent claim may not depend from another multiple dependent claim and must refer to other claims in the alternative only. The Action states that claims 5, 7, 42, 43, 53, and 54 have not been further treated on the merits, and that the previous treatment of these claims on the merits was improper, and therefore, that the prior rejection of these claims has been withdrawn. The Action also states that if the improper dependency is corrected, the previous grounds of rejection will be reinstated.

In an effort to expedite prosecution of this application to allowance, and since the objection is formal in nature whereas the withdrawn rejections were of a substantive nature, Applicants will address the withdrawn rejections as if they remain asserted against the claims as amended to overcome the formalities objection. In this way Applicants hope to avoid mere reassertion of these same grounds of rejection against the objected-to claims in any future Official Action.

With respect to the objected-to claims, claim 5 has been amended to recite "[a] process of producing a polypeptide encoded by the nucleic acid molecule of Claim 1, comprising culturing a recombinant host cell comprising the nucleic acid molecule of Claim 1 under suitable conditions to express the polypeptide." Claim 7 depends from claim 5, which in turn depends from claim 1. Claim 42 has been amended to recite "[a] process of producing a polypeptide encoded by the nucleic acid molecule of Claim 1, comprising culturing a recombinant host cell comprising a vector comprising the nucleic acid molecule of Claim 1 under suitable conditions to express the polypeptide." Claim 43 depends from claim 42, which in turn depends from claim 1. Claims 53 and 54 have been cancelled. Because claims 5 and 42, as amended, and claims 7 and 43 comply with 37 C.F.R. § 1.75(c), and claims 53 and 54 have been cancelled, Applicants respectfully request that this objection be withdrawn, and that the Examiner address the withdrawn substantive grounds of rejection in any Action that may issue resulting from the instant response.

2. Rejection of claims 1-6, 7-13, 39, 41-43, and 49-52 under 35 U.S.C. §§ 101 and 112, first paragraph

The Office Action maintains a rejection of claims 1-6, 7-13, 39, and 41-43 and asserts a rejection of claims 49-52 under 35 U.S.C. § 101 for reasons of record set forth in the Office Action

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mailed December 2, 2005, which is referenced in the Final Office Action mailed June 27, 2006. In particular, the Action states that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The Action also maintains a rejection of claims 1-6, 7-13, 39, and 41-43 and asserts a rejection of claims 49-52 under 35 U.S.C. § 112, first paragraph. In particular, the Action states that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, and therefore, that one skilled in the art would not know how to use the claimed invention.

Applicants respectfully disagree with the Action's assertion that the instant application does not comply with the utility requirements of 35 U.S.C. §§ 101 and 112, first paragraph. The framework for evaluating whether a patent application complies with 35 U.S.C. §§ 101 and 112, first paragraph, is set forth in M.P.E.P. § 2107, which requires that "the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art." M.P.E.P. § 2107(II).

A specific utility is defined as a utility that "is specific to the subject matter claimed and can 'provide a well-defined and particular benefit to the public,'" as contrasted with a general utility that would be applicable to the broad class of the invention. M.P.E.P. § 2107.01(I)(A) (citing *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005)). The Court of Appeals for the Federal Circuit has held that "an asserted use must show that the claimed invention has a significant and presently available benefit to the public," in order to satisfy the substantial utility requirement. *Fisher*, 421 F.3d at 1371. In other words, a substantial utility defines a "real world" use. M.P.E.P. § 2107.01(I)(B). For a specific and substantial utility to be credible, it must be "believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided." M.P.E.P. § 2107.02(III)(B).

Once a claimed invention has been rejected as lacking patentable utility under 35 U.S.C. §§ 101 and 112, first paragraph, an applicant can overcome the rejection by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR § 1.132. M.P.E.P. § 2107(II). Under the framework set forth in M.P.E.P. § 2107, "[a] rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention

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would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record." *Id.* Applicants contend that the claimed invention has a specific and substantial utility and that one of ordinary skill in the art would find the specific and substantial utility to be credible. In support of this contention, Applicants hereby submit the Declaration of Dr. David Ornitz under 37 C.F.R. § 1.132, which clearly establishes that the asserted utility for the claimed invention is specific, substantial, and credible.

With regard to the specification's assertion of utility, Applicants note that the specification teaches that the new FGF polypeptides disclosed in the application share sequence similarity with other members of the FGF family (Figures 3A-3D of the application), the new murine FGF protein disclosed in the application is most closely related to FGF-4, FGF-6, and FGF-15 (page 19, lines 18-22 of the specification), the new FGF disclosed in the application is expressed primarily in the liver (page 4, line 39 to page 5, line 1; page 80, lines 14-15; and page 81, lines 2-5 of the specification), and the new FGF polypeptides disclosed in the application are secreted into the bloodstream where they would be expected to exert effects on distal sites (page 5, lines 5-7; page 77, line 27 to page 78, line 1; and page 79, lines 22-26 of the specification). In addition, the specification also teaches a specific phenotype expressed by transgenic mice expressing an FGF transgene of the invention (page 4, lines 22-28 of the specification). In particular, transgenic mice expressing the FGF transgene exhibit an abnormal phenotype generally characterized as inhibited or delayed maturation, including reduced body weight, reduced liver weight as a percent of body weight, reduced spleen weight as percent of body weight, increased thymic weight as percent of body weight, and poorly developed ovaries with lack of significant follicular development.

The specification also teaches that the new FGF molecules disclosed in the application can be used to regulate growth, differentiation, and stimulation of cells within or near the liver (page 2, line 20; page 2, line 29-30; page 3, lines 8-9 and lines 26-27; and page 5, lines 7-8). In addition, the specification teaches that the new FGF molecules disclosed in the application can be used as growth or fat deposition inhibitors (page 5, lines 15-16) or in the treatment or diagnosis of liver-related diseases and disorders (page 5, lines 23-25 and page 71, lines 4-5).

Turning to Dr. Ornitz' Declaration, Applicants note that Dr. Ornitz states that after reading the application, he clearly recognized that it disclosed a new member of the FGF family that was

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unknown prior to the filing of the instant application. Ornitz Declaration, ¶ 5. Dr. Ornitz based this conclusion on two observations: first, that the sequence of the new FGF disclosed in the application is more like other FGFs than any other molecule, and second, that the conserved FGF core domain, which is found in all FGFs, is present in the new FGF disclosed in the application. *Id.* In fact, upon review of the sequence of the new FGF presented in Figure 3A-3D of the application, Dr. Ornitz identified specific residues (*i.e.*, residues 99, 100, 140, 161, 176, 183 and 186) that were known, at the time of filing of the application, to be conserved in most FGFs, and to define the FGF family. *Id.* Dr. Ornitz states that in view of the above, he was able to conclude that the new FGF disclosed in the application is in fact a member of the FGF family of proteins. *Id.*

Dr. Ornitz also states that after reading the application, he clearly recognized that the new human and murine FGFs disclosed in the application are orthologs. *Id.* at ¶ 6. Dr. Ornitz based this conclusion on two observations: first, that the new human and murine FGFs disclosed in the application share a high degree of sequence identity, and second, that the specification shows that the genes encoding these new FGFs are both strongly expressed in the liver, an expression pattern unknown for any other FGF. *Id* at ¶¶ 6 and 8.

Dr. Ornitz also clearly recognized that the experiments involving transgenic animals overexpressing the new FGF disclosed in the application were actually performed. *Id.* at ¶ 7. Dr. Ornitz based this conclusion on the observation that the experimental results presented in the application identify a phenotype that appears to result from transgenic overexpression of the new FGF disclosed in the application in multiple lines of mice. *Id.*

With respect to the specific and substantial utility of the new FGF disclosed in the application, Dr. Ornitz states that based on his review of the specification, the new FGF disclosed in the application could be used, in one example, as a diagnostic molecule for assessing liver function. *Id.* at ¶ 9. Dr. Ornitz' conclusion is also based on data presented in the application which indicated that the new human and murine FGFs disclosed in the application were strongly expressed in liver, would be typically secreted, and possessed sequences that are unique enough to permit the isolation of monoclonal or polyclonal antibodies for use in detecting the presence of the new FGF in the bloodstream, bile, or other bodily fluids. *Id.* Thus, in view of Dr. Ornitz' statements, Applicants' specification sets forth at least one reasonable and beneficial use for the claimed invention, and

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according to the M.P.E.P., "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." M.P.E.P. § 2107.01(I)(B).

Dr. Ornitz also states that based on his review of the application, the new FGF disclosed in the application could be used as a regulator of metabolic activity and as a therapeutic molecule in the treatment of a variety of metabolic diseases. Ornitz Declaration, ¶ 8. In particular, Dr. Ornitz states that the new FGF disclosed in the application could be used to treat diabetes and obesity. *Id.* Dr. Ornitz based this conclusion on five factors. First, Dr. Ornitz noted that the transgenic animals disclosed in the application had a systemic phenotype, indicating that the new FGF disclosed in the application had distal effects. *Id.* Second, the specification teaches that the new FGF disclosed in the application was expressed in liver and possessed an identified signal peptide, indicating that the new FGF would be secreted into the bloodstream or the intestine, and therefore, would likely act on tissues outside the liver. *Id.* In his Declaration, Dr. Ornitz states that while these teachings constituted a novel concept at the time the application was filed, they are fully supported by the data presented in the application, and in particular, by the phenotype of the transgenic mice. *Id.* Third, because Dr. Ornitz has concluded that the molecule disclosed in the specification was a new member of the FGF family, *id.* at ¶ 5, the new FGF would have the properties of other FGFs, such as the ability to activate receptors and have FGF-like effects, including affecting cell regulation, differentiation and physiology, *id.* at ¶ 8. Fourth, the new FGF disclosed in the application was shown to act at a significant distance from its site of expression, for example, in regulating body weight and fat deposition. *Id.* Finally, based on the unique expression of the new FGF in liver, Dr. Ornitz states that the new FGF could directly regulate liver function and thereby regulate metabolic activity. *Id.*

Applicants contend that Dr. Ornitz' Declaration, which indicates that Applicants' specification contains specific and substantial assertions of utility, is sufficient to establish that the claimed invention has patentable utility since "evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true." M.P.E.P. § 2107.02(IV). Moreover, Dr. Ornitz' Declaration shows that there is a reasonable correlation between the specification's teachings regarding the new FGF (including the activities of

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the transgene) and the specification's assertions of utility, and "as the courts have repeatedly held, all that is required is a *reasonable correlation* between the activity and the asserted use." M.P.E.P. § 2107.03(I) (emphasis added).

With respect to the instant Action's assertion that the application merely lists "a variety of unrelated diseases that the instant invention 'may' be useful in diagnosing or treating," Dr. Ornitz states that as a result of his research on FGF signaling, he has identified functions of FGFs that are both stimulatory and inhibitory for different cellular processes. Ornitz Declaration, ¶ 10. Dr. Ornitz states, therefore, that based on the phenotype of the transgenic mice expressing the new FGF disclosed in the application, it is not surprising that one property of the new FGF is to inhibit growth or metabolic activity and thus cause weight loss. *Id.* Moreover, the M.P.E.P. recognizes that while "[i]t is common and sensible for an applicant to identify several specific utilities for an invention, . . . additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility," since "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112." M.P.E.P. § 2107.02(I).

Finally, with respect to whether the assertion of specific and substantial utility for the claimed invention would be believable to a person of ordinary skill in the art, Applicants note that Dr. Ornitz has been actively working in the field of FGF and FGFR research for nearly two decades. Ornitz Declaration, ¶ 4. In addition, among Dr. Ornitz' many accomplishments, he (1) discovered FGFR3 based on similarity to FGFR1, *id.* at ¶ 1; (2) demonstrated that FGF3 could cause mammary gland cancer in transgenic mice, *id.*; and (3) has authored or co-authored numerous publications related to FGFs, *id.* at ¶ 3. Clearly, Dr. Ornitz is a person of ordinary skill in the relevant art, and is a reliable source concerning what would be credible to one of ordinary skill in the art at the time the instant application was filed. Moreover, as evidenced by his Declaration, Dr. Ornitz believes that based on the teachings in the specification and knowledge in the art at the time of the filing of the application, one of ordinary skill in the art would have expected that the new FGF disclosed in the application could at least be used as a diagnostic molecule for assessing liver function, and possibly in the treatment of diabetes and obesity.

"If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on 'lack of utility' is not appropriate." M.P.E.P. § 2107.02(III)(A).

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Because Dr. Ornitz' Declaration establishes that "the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art," M.P.E.P. § 2107(II), Applicants contend that the claimed invention is supported by an assertion of a specific and substantial utility that is credible, and therefore, respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

3. Rejection of claims 1-4, 8-11, 13, 39, 41, and 49-52 under 35 U.S.C. § 102

a. GenBank Acc. No. AQ175436 as evidenced by Kennel, 1971

The Office Action maintains a rejection of claims 1, 2, 4, 8, 9, 11, and 39 and asserts a rejection of claims 49, 50, and 51 under 35 U.S.C. § 102(a) as being anticipated by GenBank Acc. No. AQ175436, which the Action states was published October 17, 1998, as evidenced by Kennel, 1971, *Progr. Nucl. Acid Res. Mol. Biol.* 11:259-301, for the reasons of record set forth in the Office Action mailed December 2, 2005. The Action mailed December 2, 2005 states that Kennel discloses that "duplexes of 25-50 paired, contiguous nucleotides, depending on G+C content, are as stable as much longer duplexes, i.e. 25-50 paired, contiguous nucleotides are all that are required for maximum stability of the duplex." The prior Action also states that GenBank Acc. No. AQ175436 discloses a nucleic acid molecule in which nucleotides 128-483 are more than 93% identical to nucleotides 1-356 of SEQ ID NO: 1. The prior Action further states that nucleotides 128-303 of GenBank Acc. No. AQ175436 are identical to nucleotides 1-176 of SEQ ID NO: 1, and that nucleotides 128-378 of GenBank Acc. No. AQ175436 differ from nucleotides 1-251 of SEQ ID NO: 1 by three single nucleotide mismatches. The prior Action asserts that the nucleic acid molecule of GenBank Acc. No. AQ175436 would hybridize to the nucleotide sequence of SEQ ID NO: 1 under the most stringent of hybridization conditions.

To support a rejection under 35 U.S.C. § 102, "the four corners of a single, prior art document [must] describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994). The exclusion of even a single claimed element from a reference, no matter how insubstantial or obvious, is enough to negate

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anticipation. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983). The identical invention must also be shown in the single prior art reference in as complete detail as contained in the application against which the reference is cited. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Applicants respectfully disagree with the Action's assertion that GenBank Acc. No. AQ175436, as evidenced by Kennel, 1971, anticipates claims 1, 2, 4, 8, 9, 11, 39, and 49-51. However, solely in an effort to expedite prosecution of the pending claims to allowance, Applicants have deleted subpart (d) of claim 1 and have cancelled claims 39 and 49-51. Because GenBank Acc. No. AQ175436 fails to disclose the nucleic acid molecule of amended claim 1, from which claims 2, 4, 8, 9, and 11 directly or indirectly depend, and claims 39 and 49-51 have been cancelled, GenBank Acc. No. AQ175436 does not describe every element of the claimed invention. Applicants, therefore, contend that GenBank Acc. No. AQ175436 cannot anticipate the claimed invention, and respectfully request that this ground of rejection be withdrawn.

Applicants reserve the right to pursue claims directed to the deleted or cancelled subject matter in a timely filed continuation or divisional application, or alternatively, reintroduce subpart (d) or the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance.

b. GenBank Acc. No. AV050323 as evidenced by Kennel, 1971

The Office Action maintains a rejection of claims 1 and 39 under 35 U.S.C. § 102(a) as being anticipated by GenBank Acc. No. AV050323, which the Action states was published June 22, 1999, as evidenced by Kennel, 1971, *Progr. Nucl. Acid Res. Mol. Biol.* 11:259-301, for the reasons of record set forth in the Office Action mailed December 2, 2005. The Action mailed December 2, 2005 states that Kennel discloses that "duplexes of 25-50 paired, contiguous nucleotides, depending on G+C content, are as stable as much longer duplexes, i.e. 25-50 paired, contiguous nucleotides are all that are required for maximum stability of the duplex." The prior Action also states that GenBank Acc. No. AV050323 discloses a nucleic acid molecule in which nucleotides 1-604 are more than 93% identical to nucleotides 437-640 of SEQ ID NO: 3. The prior Action also states that the nucleic acid molecule of GenBank Acc. No. AV050323 comprises regions of 29, 55, and 59

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nucleotides that are identical to regions of the nucleotide sequence of SEQ ID NO: 1. The prior Action asserts that the nucleic acid molecule of GenBank Acc. No. AV050323 would be expected to hybridize to the nucleotide sequence of SEQ ID NO: 3 under the most stringent of hybridization conditions.

Applicants respectfully disagree with the Action's assertion that GenBank Acc. No. AV050323, as evidenced by Kennel, 1971, anticipates claims 1 and 39. However, solely in an effort to expedite prosecution of the pending claims to allowance, Applicants have deleted subpart (d) of claim 1 and have cancelled claim 39. Because GenBank Acc. No. AV050323 fails to disclose the nucleic acid molecule of amended claim 1, and claim 39 has been cancelled, GenBank Acc. No. AV050323 does not describe every element of the claimed invention. Applicants, therefore, contend that GenBank Acc. No. AV050323 cannot anticipate the claimed invention, and respectfully request that this ground of rejection be withdrawn.

Applicants reserve the right to pursue claims directed to the deleted or cancelled subject matter in a timely filed continuation or divisional application, or alternatively, reintroduce subpart (d) or the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance.

c. GenBank Acc. No. AV050323 as evidenced by Kennel, 1971 and GenBank Acc. No. AQ175436

The Office Action maintains a rejection of claims 2, 4, 8, 9, and 11 and asserts a rejection of claims 49, 50, and 51 under 35 U.S.C. § 102(a) as being anticipated by GenBank Acc. No. AV050323, which the Action states was published June 22, 1999, as evidenced by Kennel, 1971, *Progr. Nucl. Acid Res. Mol. Biol.* 11:259-301 and GenBank Acc. No. AQ175436, for the reasons of record set forth in the Office Action mailed December 2, 2005. The Action mailed December 2, 2005 states that Kennel discloses that "duplexes of 25-50 paired, contiguous nucleotides, depending on G+C content, are as stable as much longer duplexes, i.e. 25-50 paired, contiguous nucleotides are all that are required for maximum stability of the duplex." The prior Action also states that GenBank Acc. No. AV050323 discloses a nucleic acid molecule in which nucleotides 1-604 are more than 93% identical to nucleotides 437-640 of SEQ ID NO: 3. The prior Action also states that

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the nucleic acid molecule of GenBank Acc. No. AV050323 comprises regions of 29, 55, and 59 nucleotides that are identical to regions of the nucleotide sequence of SEQ ID NO: 1. The prior Action acknowledges that GenBank Acc. No. AV050323 does not provide any details on clone 1810013H18, but asserts that the standard method for preparing such clones, as exemplified in GenBank Acc. No. AQ175436, is to insert the cDNA into a bacterial plasmid that is then used to transform a suitable strain of *E. coli*.

Applicants respectfully disagree with the Action's assertion that GenBank Acc. No. AV050323, as evidenced by Kennel, 1971, anticipates claims 2, 4, 8, 9, 11, and 49-51. However, solely in an effort to expedite prosecution of the pending claims to allowance, Applicants have deleted subpart (d) of claim 1 and have cancelled claims 49-51. Because GenBank Acc. No. AV050323 fails to disclose the nucleic acid molecule of amended claim 1, from which claims 2, 4, 8, 9, and 11 directly or indirectly depend, and claims 49-51 have been cancelled, GenBank Acc. No. AV050323 does not describe every element of the claimed invention. Applicants, therefore, contend that GenBank Acc. No. AV050323 cannot anticipate the claimed invention, and respectfully request that this ground of rejection be withdrawn.

Applicants reserve the right to pursue claims directed to the deleted or cancelled subject matter in a timely filed continuation or divisional application, or alternatively, reintroduce subpart (d) or the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance.

d. U.S. Patent No. 6,639,063

The Office Action maintains a rejection of claims 1-4, 8-11, 13, 39, and 41 and asserts a rejection of claims 49-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,639,063 ('063 patent), which the Action states claims priority to U.S. Provisional Application No. 60/147,499, filed August 5, 1999, for the reasons of record set forth in the Office Action mailed December 2, 2005. The Action mailed December 2, 2005 states that the '063 patent discloses a nucleic acid molecule (SEQ ID NO: 1353) that encodes a polypeptide (SEQ ID NO: 5213) that comprises amino acids 1-79 of SEQ ID NO: 2 of the instant application. The prior Action also states that nucleotides 28-477 of SEQ ID NO: 1353 differ from nucleotides 1-451 of SEQ ID NO: 1 of the

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instant application by two mismatched nucleotides. The prior Action asserts that the nucleotide sequence of SEQ ID NO: 1353 would hybridize to the nucleotide sequence of SEQ ID NO: 1 of the instant application under the most stringent of hybridization conditions.

Applicants respectfully disagree with the Action's assertion that the '063 patent anticipates claims 1-4, 8-11, 13, 39, 41, and 49-52. However, solely in an effort to expedite prosecution of the pending claims to allowance, Applicants have deleted subpart (d) of claim 1 and have cancelled claims 39 and 49-52 (claim 13 was deleted in Applicants' response to the Office Action mailed December 2, 2005). Because the '063 patent fails to disclose the nucleic acid molecule of amended claim 1, from which claims 1-4, 8-11, and 41 directly or indirectly depend, and claims 13, 39, and 49-52 have been cancelled, the '063 patent does not describe every element of the claimed invention. Applicants, therefore, contend that the '063 patent cannot anticipate the claimed invention, and respectfully request that this ground of rejection be withdrawn.

Applicants reserve the right to pursue claims directed to the deleted or cancelled subject matter in a timely filed continuation or divisional application, or alternatively, to reintroduce subpart (d) or the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance.

Applicants contend that the rejections based on 35 U.S.C. § 102 have been overcome by amendment, and respectfully request that the Examiner withdraw all rejections made on this basis.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited. Applicants remind the Examiner of U.S. Patent No. 6,716,626, which issued on April 6, 2004 from U.S. Application No. 09/715,805, filed November 16, 2000, and which claims the benefit of U.S. Provisional Application Nos. 60/203,633, filed May 11, 2000, and 60/166,540, filed November 18, 1999. Applicants further remind the Examiner that they have an earlier filing date and believe that they are the first and sole inventors of the claimed subject matter, and therefore, expect the Examiner to declare an interference if the pending claims are found to be allowable.

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If Examiner Priebe believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
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Dated: July 23, 2007

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